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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/706,685   | 11/12/2003  | James F. McGuckin JR. | 1238DIV             | 7009             |
| 7590<br>NEIL D. GERSHON<br>REX MEDICAL<br>1011 HIGH RIDGE RD<br>Stamford, CT 06905 |             |                       |                     |                  |
| 01/21/2009   |             |                       |                     |                  |
| EXAMINER   |             |                       |                     |                  |
| SCHILLINGER, ANN M   |             |                       |                     |                  |
| ART UNIT   |             | PAPER NUMBER          |                     |                  |
| 3774   |             |                       |                     |                  |
| MAIL DATE  |             | DELIVERY MODE         |                     |                  |
| 01/21/2009   |             | PAPER                 |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/706,685

**Applicant(s)**

MCGUCKIN ET AL.

**Examiner**

ANN SCHILLINGER

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 31-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5, 6, 8-12, 15, 16, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Frantzen et al. (US Pat. No. 5,843,164) in view of Andersen et al. (US Pat. No. 5,840,081). Frantzen et al. discloses the following of the claimed invention: a vascular device comprising a plurality of vessel engaging members with penetrating tips (20) that pierce the vessel wall. The device is movable from a collapsed insertion position having a first diameter to a second expanded position having a second diameter larger than the first diameter via a balloon catheter (62). When the balloon is deflated and removed, the device will inherently pull inwardly on the vessel wall as it moves towards its third expanded diameter. Please see Figures 2, 3, and 9-11. The device may be made of stainless steel (col. 5, lines 57-58).

Frantzen et al. does not teach including a valve with the vascular device. Andersen et al. teaches a vascular stent that is used to deliver a valve in col. 2, lines 20-65 for the purpose of providing a needed valve to its desired location without major surgical intervention. The valve includes a proximal opening (side nearest element 4) and a distal opening (side nearest element 25), and a reinforcement ring (25) adjacent the distal opening. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a

valve with the device of Frantzen et al. in order to provide a patient with a needed valve without major surgical intervention.

Claims 2-4, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. in view of Andersen et al., further in view of Flomenbilt et al. (US Pat. No. 5876434). Frantzen et al., as modified by Andersen et al., teaches the invention substantially as claimed, however, they do not teach the use of shape memory material with exposure to body temperature to control the alterations of the device. Flomenbilt et al. teaches shape memory material and exposure to body temperature in col. 2, lines 37-65 and col. 4, line 66 through col. 5, line 15 for the purpose of causing the device to assume the necessary configuration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shape memory material with exposure to body temperature in order to cause the device to assume the necessary configuration.

Claims 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frantzen et al. in view of Andersen et al., further in view of Wilson et al. (US Pat. No. 5876434). Frantzen et al., as modified by Andersen et al., teaches the invention substantially as claimed, however, they do not teach the use of blood drainage openings. Wilson et al. teaches these openings in col. 2, lines 42-65 and col. 3, line 66 through col. 4, line 7 for the purpose of relieving excess pressure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use these openings in order to relieve excess pressure.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-17 and 31-33 have been considered but are moot in view of the new ground(s) of rejection. As stated above, the stainless steel stent of

Frantzen et al. will inherently pull back on the vessel wall after the deflation of the expansion balloon. Claims 1 and 12 also contain functional language that is a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus. Therefore, this language is not given patentable weight. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. S./  
Examiner, Art Unit 3774

/William H. Matthews/  
Primary Examiner, Art Unit 3774

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